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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,014	06/27/2001	Hylar L. Friedman	PC10841AMAG	6389

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/20/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
	09/893,014 FRIEDMAN ET AL.
Examiner	Art Unit
Shaojia A. Jiang	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 August 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,7 and 8 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,5,6 and 9-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4-5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application claims priority to provisional application Serial No. 60/214,979.

Applicant's amendment filed August 21, 2002 in response to the Restriction Requirement (April 23, 2002) wherein claims 21-41 are cancelled, has been entered in Paper 8.

Election/Restrictions

Applicant's election without traverse of the invention of the species of claims 5-6, in Paper No. 8 submitted August 21, 2002 is acknowledged.

Claims 3-4 and 7-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected species.

The claims have been examined insofar as they read on the elected specie.

Claim Objection

Claims 13 and 14 are objected to for minor informalities. The employment of parenthetical expressions e.g., "(SSRI)" and "(MAO)" in the claims is considered informal. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-11 and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expressions "elderly", "acutely ill", "chronically ill", immunocomprised" and immuno suppressed" in claim 10 render the claim indefinite since the scope of claims is indefinite as to the "elderly", "acutely ill", "chronically ill", immunocomprised" and immuno suppressed" encompassed thereby. These expressions are not defined by the claims and specification. Thus, these expressions in the claims fail clearly set forth the metes and bounds of the patent protection desired.

Claims 11 and 15-16 contain the trademark/trade name GHRP-1, GHRP-2, IGF-I, IGF-II and SSRI. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe particular active agents herein and, accordingly, the identification/description is indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by CARPINO et al. (WO 98/58947, PTO-1449 submitted June 27, 2001).

The instant invention is drawn to employ the instant compounds of structural formula (I) alone or in combination of a growth hormone secretagogue selected from GHRP-6, GHRP-1, hexarelin and IGF-1, and IGF-II in a method for stimulating or increasing appetite in a patient.

CARPINO et al. discloses that the instant compounds of the structural formula (I) which covers the instant elected species, being growth hormone secretagogues, are useful in a pharmaceutical composition and methods for increasing levels of endogenous growth hormone and treating medical disorders associated to deficiency in growth hormone such as osteoporosis, frailty associated with aging, and obesity, in a human. CARPINO et al. also discloses the employment of the active compounds therein in combination of a growth hormone secretagogue selected from GHRP-6, GHRP-1, hexarelin and IGF-1, and IGF-II. See the abstract, page 1-28, page 52-59, and claims 77-106. CARPINO's method inherently stimulating or increasing appetite in a patient, as claimed herein since CARPINO's method steps are same as the instant method steps. Note that the amount of active compounds to be administered to a patient in instant invention is same as in CARPINO et al. See *Ex parte Novitski*, 26 USPQ 2d 1389.

Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein. Thus, CARPINO et al. anticipates claim 1 and 9-11.

Claims 1-2, 5-6 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by CARPINO et al. (WO 97/24369, PTO-1449 submitted June 27, 2001).

The instant invention is drawn to employ the instant compounds of structural formula (I) and (I-A) alone or in combination of a growth hormone secretagogue selected from GHRP-6, GHRP-1, hexarelin and IGF-1, and IGF-II in a method for stimulating or increasing appetite in a patient.

CARPINO et al. discloses that the instant compounds of the structural formula (I) which covers the instant elected species, which are growth hormone secretagogues, are useful in a pharmaceutical composition and methods for increasing levels of endogenous growth hormone and treating medical disorders associated to deficiency in growth hormone such as osteoporosis, frailty associated with aging, and obesity, in a human. See the abstract, page 1-2, page 4-11, page 17 lines 1-5, and claims 49-60. CARPINO et al. also discloses the employment of the active compounds therein in combination of a growth hormone secretagogue selected from GHRP-6, GHRP-1, hexarelin and IGF-1, and IGF-II. CARPINO's method inherently stimulating or increasing appetite in a patient, as claimed herein since CARPINO's method steps are

same as the instant method steps. Note that the amount of active compounds to be administered in instant invention to a patient is same as in CARPINO et al. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein. Thus, CARPINO et al. anticipates claim 1-2, 5-6 and 9-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-16 even though they are not anticipated by CARPINO et al. reference (WO 98/5894 or WO 97/24369) as stated above in the 102(b) rejections, are rejected under 35 U.S.C. 103(a) as being unpatentable over the same references by CARPINO et al. in view of Vaccarino et al. (CA 2095788, PTO-1449 submitted March 25, 2002) and The Merck Manual of Diagnosis and Therapy (16th ED) page 1529-1534.

Claims 12-16 are drawn to employ the instant compounds of structural formula (I) and (I-A) in combination of an antidepressant herein such as SSRI, MAO and atypical antidepressant, in a method for stimulating or increasing appetite in a patient.

CARPINO et al. discloses that the instant compounds of the structural formula (I) which covers the instant elected species, which are growth hormone secretagogues, are useful in a pharmaceutical composition and methods for increasing levels of endogenous growth hormone and treating medical disorders associated to deficiency in growth hormone such as osteoporosis, frailty associated with aging, and obesity, in a human. See the abstract, page 1-2, page 4-11, page 17 lines 1-5, and claims 49-60. CARPINO et al. also discloses the employment of the active compounds therein in combination of a growth hormone secretagogue selected from GHRP-6, GHRP-1, hexarelin and IGF-1, and IGF-II.

CARPINO et al. does not expressly disclose the employment of the instant compounds of structural formula (I) and (I-A) in combination of an antidepressant herein such as SSRI, MAO and atypical antidepressant, in a method for stimulating or increasing appetite in a patient.

Vaccarino et al. discloses that a growth hormone secretagogue or a growth hormone-releasing factor is known to be useful in a method for treating appetite disorder in a patient or stimulating appetite in a patient.

The Merck Manual of Diagnosis and Therapy (16th ED) teaches that an antidepressant herein such as SSRI, MAO and atypical antidepressant is known to be useful in the treatment of depression in a patient and decreasing appetite or anorexia is known to one of characteristic symptoms of depression. See page 1529-1534.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant compounds of structural formula (I) and (I-A)

in combination of an antidepressant herein such as SSRI, MAO and atypical antidepressant, in a method for stimulating or increasing appetite in a patient.

One having ordinary skill in the art at the time the invention was made would have been motivated to the instant compounds of structural formula (I) and (I-A) in combination of an antidepressant herein such as SSRI, MAO and atypical antidepressant, in a method for stimulating or increasing appetite in a patient, since a growth hormone secretagogue or a growth hormone-releasing factor is known to be useful in a method for treating appetite disorder in a patient or stimulating appetite in a patient based on the prior art. Therefore, one of ordinary skill in the art would have reasonably expected that the instant compounds of the structural formula (I) formula (I) and (I-A) which are known growth hormone secretagogues, would be useful in method for treating appetite disorder in a patient or stimulating appetite in a patient. Moreover, an antidepressant herein such as SSRI, MAO and atypical antidepressant is well known to be useful in a method of the treatment of decreasing appetite or anorexia, a known characteristic symptom of depression in a patient according to The Merck Manual of Diagnosis and Therapy (16th ED). Therefore, one of ordinary skill in the art would have reasonably expected that combining the instant compounds of structural formula (I) and (I-A) in combination of an antidepressant herein known to be useful individually for the same purpose, i.e., stimulating or increasing appetite in a patient, in a pharmaceutical composition to be administered would improve the therapeutic effect for stimulating or increasing appetite.

Since all active composition components herein are known to useful to stimulate or increase appetite, it is considered *prima facie* obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Claims 17-20 even though they are not anticipated by CARPINO et al. reference (WO 98/5894 or WO 97/24369) as stated above in the 102(b) rejections, are rejected under 35 U.S.C. 103(a) as being unpatentable over the same references by CARPINO et al. in view of Vaccarino et al. (CA 2095788, PTO-1449 submitted March 25, 2002) and The Merck Manual of Diagnosis and Therapy (16th ED) page 1529-1534, and The Pharmacological Basis of Therapeutics (1996) page 928-932 and 339-430 (see also the specification regarding prior art at 36-37).

Claims 17-20 are drawn to employ the instant compounds of structural formula (I) and (I-A) in combination of an antiemetic herein or antipsychotic, in a method for stimulating or increasing appetite in a patient.

CARPINO et al. discloses that the instant compounds of the structural formula (I) which covers the instant elected species, which are growth hormone secretagogues, are useful in a pharmaceutical composition and methods for increasing levels of endogenous growth hormone and treating medical disorders associated to deficiency in growth hormone such as osteoporosis, frailty associated with aging, and obesity, in a

human. See the abstract, page 1-2, page 4-11, page 17 lines 1-5, and claims 49-60. CARPINO et al. also discloses the employment of the active compounds therein in combination of a growth hormone secretagogue selected from GHRP-6, GHRP-1, hexarelin and IGF-1, and IGF-II.

CARPINO et al. does not expressly disclose the employment of the instant compounds of structural formula (I) and (I-A) in combination of an antiemetic herein or antipsychotic, in a method for stimulating or increasing appetite in a patient.

Vaccarino et al. discloses that a growth hormone secretagogue or a growth hormone-releasing factor is known to be useful in a method for treating appetite disorder in a patient or stimulating appetite in a patient.

An antiemetic herein or antipsychotic is known to be useful in treating decreasing appetite or anorexia in depression according to The Merck Manual of Diagnosis and Therapy (16th ED) and The Pharmacological Basis of Therapeutics (1996) page 928-932 and 339-430 (see also the specification regarding prior art at page 36-37).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant compounds of structural formula (I) and (I-A) in combination of an antiemetic herein or antipsychotic herein, in a method for stimulating or increasing appetite in a patient.

One having ordinary skill in the art at the time the invention was made would have been motivated to the instant compounds of structural formula (I) and (I-A) in combination of an antidepressant herein such as SSRI, MAO and atypical antidepressant, in a method for stimulating or increasing appetite in a patient, since a

growth hormone secretagogue or a growth hormone-releasing factor is known to be useful in a method for treating appetite disorder in a patient or stimulating appetite in a patient based on the prior art. Therefore, one of ordinary skill in the art would have reasonably expected that the instant compounds of the structural formula (I) formula (I) and (I-A) which are known growth hormone secretagogues, would be useful in method for treating appetite disorder in a patient or stimulating appetite in a patient. Moreover, an antiemetic herein or antipsychotic herein is well known to be useful in a method of the treatment of decreasing appetite or anorexia, a known characteristic symptom of depression in a patient according to The Merck Manual of Diagnosis and Therapy (16th ED) and The Pharmacological Basis of Therapeutics (1996) page 928-932 and 339-430. Therefore, one of ordinary skill in the art would have reasonably expected that combining the instant compounds of structural formula (I) and (I-A) in combination of an antiemetic herein or antipsychotic herein known to be useful individually for the same purpose, i.e., stimulating or increasing appetite in a patient, in a pharmaceutical composition to be administered would improve the therapeutic effect for stimulating or increasing appetite.

Since all active composition components herein are known to be useful to stimulate or increase appetite, it is considered *prima facie* obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. A. Jiang, Ph.D.
Patent Examiner, AU 1617
November 11, 2002


SCREENI PADMANABHAN
PRIMARY EXAMINER 